PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
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PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	01 NOV 2005
Applicant's or agent's file reference NAGACO.072VP	**FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US04/23891	22 July 2004 (22.07.2004)	25 July 2003 (25.07.2003)

International Patent Classification (IPC) or both national classification and IPC

IPC(7): B01L 11/00 and US Cl.: 422/100; 422/101; 422 100.72; 435/288.5

Applicant

NAGAOKA & CO. LTD

1. This opinion contains indications relating to the following items:

- ☒ Box No. I — Basis of the opinion
- ☐ Box No. II — Priority
- ☐ Box No. III — Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV — Lack of unity of invention
- ☒ Box No. V — Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI — Certain documents cited
- ☐ Box No. VII — Certain defects in the international application
- ☐ Box No. VIII — Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(*b*) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US	Date of completion of this opinion	Authorized officer
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	11 September 2005 (11.09.2005)	Julie E. Burke Valerie Bell-Harris for Telephone No. (571) 272-1600

Form PCT/ISA/237 (cover sheet) (April 2005)

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US04/23891

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:

☒ the international application in the language in which it was filed

☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☐ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ on paper

☐ in electronic form

c. time of filing/furnishing

☐ contained in the international application as filed.

☐ filed together with the international application in electronic form.

☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

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International application No.
PCT/US04/23891

Box No. V Reasoned statement under Rule 43 *bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 4-10	YES
	Claims 1-3	NO
Inventive step (IS)	Claims NONE	YES
	Claims 1-10	NO
Industrial applicability (IA)	Claims 1-10	YES
	Claims NONE	NO

2. Citations and explanations:

Please See Continuation Sheet

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

Supplemental Box
In case the space in any of the preceding boxes is not sufficient.

V. 2. Citations and Explanations:
Claims 1-3 lack novelty under PCT Article 33 (2) as anticipated by Nelson et al. (US 6344326).

Nelson discloses an integrated microfluidic device in one of the embodiments comprising(as shown in Figure 6) reservoir 96 having sample introduction means ['loading chamber with inlet' - Examiner], reservoir 98 ['separation chamber' - Examiner) fluidically connected to the loading chamber 96 via channel 97 ['sample pass through channel' - Examiner], and channel 95 [sample flow channel' - Examiner], linking the sample pass through channel' 97 to reservoir 85 ['analysis chamber'- Examiner] through region 91 ['mixing chamber' -Examiner-(See Figure 6., Col. 13, lines 50-65).

With respect to claim 3, Nelson teaches that as an optional component that may be present in the subject devices is a waste fluid. reservoir for receiving and storing the waste portion of the initial sample volume from the enrichment channel, where the waste reservoir will be in fluid communication with the discharge outlet. Depending on the particular device configuration, the discharge outlet maybe the same as, or distinct from, the waste outlet, and may open into a waste reservoir or provide an outlet from the device. The waste reservoir may be present in the device as a channel, compartment, or other convenient configuration which does not interfere with the other components of the device'(Col.10, lines 20-30).

Claims 1 -10 lack inventive step under Article 33 (3) as obvious over Petersen et al. (US 6881541).

Petersen discloses fluidic structures device in one of the embodiments (àhown in Figure 9) comprising chamber 65 ['loading chamber with inlet' - Examiner] in fluid communication with chamber 67 ['separation chamber' - Examiner'] via channel 1 17 ['sample pass through channel' Examiner]. The sample flow chnnnel' has its first end 106 connected to the sample pass through channel' 117 and its second end 110 connected to chamber 68 [analysis chamber' -Examiner] via section 1 12 ['mixing chnmber' - Examiner].

lt is noted that Petersen et al. does not specifically teach channel 112 to be a mixing chamber. However, Applicant's claims do not recite any structure for the 'mixing chamber' or the analysis chamber' which distinguishes over the channel of Petersen. Clearly, the structures are capable of operating as a mixing chamber and an analysis chamber. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have employed the above elements in the structure of Peterson, in order to provide mixing and analyzing the substances.

With respect to claim 3, although chamber 68 (which can be used as analysis chamber) is not shown to be further connected to a vent outlet comprising a channel and a port the aforementioned elements are routinely used in the art, and it would have been obvious to one of ordinary skill in the art at the time the invention was made to have employed venting means linked to the analysis chamber in the structure of Peterson, in order to provide waste removal. Referring to claim 4, Figure 9 further shows chamber 70 ('buffer loading chamber with inlet' - Examiner) in fluid communication with the first end of an unmarked channel section accommodating valve 124 ['buffer pass through channel' - Examiner], the second end of the 'buffer pass through channel' intersecting an unmarked channel section connected to the first end of section 112 ['mixing chamber'].

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Supplemental Box
In case the space in any of the preceding boxes is not sufficient.

As to claim 5 and 7, Figure 9 further indicates chamber 66 ['sample waste chamber' -Examiner) connected to the sample pass through channel' 117 via a channel section accommodating valve 115 [sample waste channel' - Examiner]. Although chambers 66 and 67 are not shown to be further connected to vent outlets comprising a channel and a port, the aforementioned elements are routinely used in the art, and it would have been obvious to one of ordinary skill in the art at the time the invention was made to have employed venting means linked to the sample waste chamber and to the sample separation chamber in the structure of Peterson, in order to provide proper waste removal.

In regards to claim 6, Figure 9 shows chamber 42 ['buffer waste chamber' - Examiner] being connected to the 'buffer pass through channel' via 122 / 80 [buffer waste channel'-Examiner], channel 131/132/134 ['buffer waste yent channel' - Ex.] and port 36 [buffer vent port' - Ex.]. .

Referring to claims 8-10, capillary valves are located at all junctions between the major functional segments of the fluidic structure, for example, valves 119, 11 and 124 can be regarded as claimed first, second and third valve correspondingly.

Claims 1-10 meet the criteria set in PCT Article 33 (4) for industrial applicability because the claimed invention can be used or made for industry.